UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,344	11/21/2005	Dirk Mertin	LeA 36165	9502

71285 7590 12/22/2009

BAYER HEALTHCARE LLC
P.O.BOX 390
SHAWNEE MISSION, KS 66201

EXAMINER	
DICKINSON, PAUL W	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
12/22/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

janis.wright.b@bayer.com
jessica.monachello.b@bayer.com
andrea.ewell.b@bayer.com

Office Action Summary	Application No.	Applicant(s)	
	10/516,344	MERTIN ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3 and 11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 9/22/2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 103

The declaration under 37 CFR 1.132 filed 9/22/2009 is insufficient to overcome the rejection of claims 1, 3, 11-19 under 35 U.S.C. 103(a) as being unpatentable over US 5152986 ('986) in view of US 6323213 ('213).

Applicant argues the following points: (1) The addition of thickeners in '986 is optional and several possible thickeners are disclosed. (2) The present invention has a gel-type 3-dimensional structure which helps to prevent sedimentation. Certain pseudoplastic gel formers (thickeners) would not provide adequate yield points and shear viscosity, i.e. proper stability to sedimentation, as in the present liquid formulation. The instant composition is particularly well accepted and tolerated after oral administration. The art does not specifically refer to the problem of preparing a liquid formulation with a good mouthfeel. (3) Further, '986 teaches that the thickeners are added to make semi-solid preparations or oral pastes which teaches away from the present invention that includes water as the carrier.

Applicant's arguments have been fully considered but are not found persuasive.

(1) It would have been obvious to add a thickener from the list recited by '986, such as xanthan gum, as this is one embodiment taught by the reference to afford quinolonecarboxylic acid formulations with improved taste, high uptake and high tolerance levels in animals (see col 5, lines 5-13).

(2) Applicant argues that certain thickeners (pseudoplastic gel formers) would not provide adequate yield points and shear viscosity. Applicant further argues that the art does not address the challenge of preparing a liquid formulation with a particularly good mouthfeel. The Examiner does not disagree that Applicant has made a good product with many desirable properties. The question at hand is whether Applicant's claimed product is obvious over the prior art. In other words, would it have been obvious at the time the instant invention was made to arrive at the same product as the one claimed. The Examiner maintains that the answer to this question is yes. '986 discloses ion exchange resins which are loaded with quinolonecarboxylic acid derivatives, and their preparation (see entire document; abstract; col 1, lines 9-11). The quinolonecarboxylic acids are bound to ion exchange resins, such as Lewatit® SPC 108 (an acidic ion exchange resin) and are dispersed in a aqueous carrier for administration to an animal (see col 5, lines 14-22). Bentonite (a pseudoplastic gel former) may be added to the formulation of '986 as an auxiliary agent (see col 5, lines 46-52; col 6, lines 34-37). Other pseudoplastic gel formers, such as xanthan gum, may be used to thicken the carrier into a semi-solid (a highly viscous liquid) (see col 6, lines 18-26). Accordingly, '986 is deficient only in that it does explicitly teach pradofloxacin as the quinolonecarboxylic acid derivative. This deficiency is made up for by the teaching of

'231. It would have been obvious to incorporate pradofloxacin as the quinolonecarboxylic acid in the formulation disclosed by '986, as pradofloxacin has a more potent antibacterial action than enrofloxacin and is suitable for human and veterinary medicine. That the art does not recognize the advantages of the formulation pointed out by Applicant does not distinguish Applicant's claimed invention from the prior art. "'[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.' Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." MPEP § 2112, I.

(3) Regarding Applicant's statement that '986 teaches away from the claimed invention, liquid water is a preferred carrier of '986 (see col 5, lines 59-61). Although the recited thickeners are added so that the suspension may be administered as a semi-solid, a semi-solid is a highly viscous liquid. The Examiner notes that bentonites (a presently disclosed pseudoplastic gel former) may also be added to the formulation of '986 (with or without the presence of thickeners) as an auxiliary agent (see col 5, lines 46-52; col 6, lines 34-37).

Regarding the data presented in the table of the declaration, the Examiner agrees that Formulation 5 has a higher shear viscosity than Formulations 1-4. The Examiner agrees that Formulation 5 has a yield point, whereas Formulations 1-4 do not.

However, the amounts of ingredients change from formulation to formulation, and particularly if one were to consider Formulation 1-4 as a group, their ingredients are vastly different than those in Formulation 5. For example, Formulations 1-4 all contain lactic acid, sodium hydroxide, and silica. Formulation 5 does not. Formulations 1-2 contain malt syrup. Formulation 5 does not. Formulation 5 has ascorbic acid, xanthan gum, and vanilla flavour. Formulations 1-4 do not. The amount of propylene glycol in Formulations 1-4 is 10 grams, whereas the amount of propylene glycol in Formulations 1-4 is 30 grams. There are too many variations from formulation to formulation to conclude what is controlling the viscosity and yield point. It is more reasonable that tripling the amount of propylene glycol from 10 grams to 30 grams has a larger impact on the viscosity than the 0.7 g of xanthan gum added. There are simply too many variations from formulation to formulation, particularly from Formulations 1-4 to Formulation 5, to draw any conclusion as to what components are controlling the viscosity and yield point. The data do not support the criticality of xanthan gum.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5152986 ('986) in view of US 6323213 ('213). '986 discloses ion exchange resins which are loaded with quinolonecarboxylic acid derivatives, and their preparation (see entire document; abstract; col 1, lines 9-11). The quinolonecarboxylic acids are bound to ion exchange resins, such as Lewatit® SPC 108 (an acidic ion exchange resin) and are dispersed in an aqueous carrier for administration to an animal (see col 5, lines 14-22). Bentonite (a pseudoplastic gel former) may be added to the formulation of '986 as an auxiliary agent (see col 5, lines 46-52; col 6, lines 34-37). '986 contemplates adding

optional excipients to the aqueous dispersion of quinolonecarboxylic acid/ion exchange resin for administration to an animal (see col 3, lines 54-56; col 5, lines 59-61). Viscosity enhancing agents, such as cellulose derivatives and xanthan gum (pseudoplastic gel formers), are optional excipients (see col 6, lines 18-26). '986 discloses several advantages of the formulation including improvement in taste and higher uptake and tolerance levels of the formulation in animal subjects relative to other quinolonecarboxylic acid formulations (see abstract; col 3, lines 36-63). Although '986 contemplates incorporating a range of quinolonecarboxylic acids in the patent invention, it fails to disclose pradofloxacin.

'213 discloses the preparation and utility of pradofloxacin (see entire document; col 2, ln 35-41; Example 1). '213 discloses that pradofloxacin has a more potent antibacterial action than other known quinolonecarboxylic acids, such as enrofloxacin, and is suitable for human and veterinary medicine (see ibid).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to combine the disclosures of '986 and '213 to afford the instant invention. Specifically, it would be obvious to incorporate pradofloxacin as the quinolonecarboxylic acid in the formulation of '986, as pradofloxacin has a more potent antibacterial action than enrofloxacin disclosed by '986 and is suitable for human and veterinary medicine. It would have been obvious to prepare an aqueous suspension of the formulation (a liquid pharmaceutical), as this is one embodiment taught by '986 that affords an effective taste masked formulation with high uptake and high tolerance levels in animal subjects.

Although '986 and '213 do not disclose all the characteristics and properties of the composition disclosed in the present claims (the yield point and viscosity), based on the substantially identical process using identical components, the Examiner has a reasonable basis to believe that the properties claimed in the present invention would be inherent in the composition prepared by the combination of '986 in view of '213. ""[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." MPEP § 2112, I.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Primary Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

December 9, 2009